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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,331	09/16/2003	Laurent Humeau	397272000401	4194
25225 7590 02/06/2008 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER PARKIN, JEFFREY S	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 02/06/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/664,331

Applicant(s)

HUMEAU ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15, 17-24, 27-30, 33-45, 47, 48, 50, 52, 53, 56-59, 61-64, 66-71, 83-90, 93, 94, 97-101 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-15,17-24,27-30,33-45,47,48,50,52,53,56-59,61-64,66-71,83-90,93,94 and 97-101.

Serial No.: 10/664,331  
Applicants: Humeau, L, et al.

Docket No.: 397272000401  
Filing Date: 09/16/2003

### **Restriction Requirement**

#### **37 C.F.R. § 1.114**

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection on 30 October, 2007. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission accompanying the filing has been entered. Claims 1-15, 17-24, 27-30, 33-45, 47, 48, 50, 52, 53, 56-59, 61-64, 66-71, 83-90, 93, 94, and 97-101 are pending in the instant application.

Applicants are reminded that pursuant to M.P.E.P. § 818.02(a) where claims to another invention are properly added and entered in the application before an action is given, they are treated as original claims for purposes of restriction only. The claims originally presented and acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination (RCE) which has been filed for the application. Subsequently presented claims to an invention other than that acted upon are generally treated as provided in M.P.E.P. § 821.03.

#### **35 U.S.C. § 121**

Applicants' amendment necessitated the following restriction requirement. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-15, 17-24, 27-30, 33-45, 47, 48, 50, 52, 53, 56-59, 61-64, 66-71, 83, 84, 88-90, 93, 94, and 97-101, drawn to *in vitro/ex vivo* methods of transducing primary lymphoid cells, myeloid cells, or hematopoietic progenitor cells using a

lentiviral vector and cell surface binding molecule, classified in class 435, subclass 456.

- b. Group II, claim(s) 85, drawn to a method for the introduction of transduced cells into a living subject, classified in class 435, subclass 325.
- c. Group III, claim(s) 86, drawn to a method for the introduction of transduced cells into a tissue or organ, classified in class 435, subclass 325.
- d. Group IV, claim(s) 87, drawn to a method for the introduction of transduced cells into a blastocyst, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant situation each of the identified groups is directed toward a different method that accomplishes different scientific objectives and employs disparate methodology steps and scientific reagents. For instance, Group I is simply directed toward a method of stably transducing hematopoietic stem cells by administering a vector and compound. However, Group II involves the administration of a transduced cell into a patient. Clearly these methodologies achieve different scientific objectives and employ different reagents/protocols.

Applicants are further advised that the following restriction requirement also applies to Group I: **1) Applicants are required to identify and elect a single cell target (i.e., one of a primary lymphoid cell, a myeloid cell, or a hematopoietic progenitor cell). The election should also include the genotypic/phenotypic characteristics of the desired cell target (i.e., one of a CD4<sup>+</sup> T-**

lymphocyte, CD34+ hematopoietic precursor, etc.). Applicants are required to identify those claims that read on the elected invention. Each of the identified cell targets has different genotypic/phenotypic characteristics and will necessitate separate searches. 2) Applicants are also required to identify and elect a single cell surface binding molecule (i.e., one of a polypeptide, lipid, nucleic acid, carbohydrate, ion, FLT-3 ligand, TPO ligand, KIT ligand; antibodies with the specificity of FLT-3L, TPOL, or KITL, CD3 ligand, CD28 ligand, CD25 ligand, CD71 ligand, CD69 ligand, antibodies with the specificity of CD3 ligand, CD28 ligand, CD25 ligand, CD71 ligand, or CD69 ligand, CD34, CD28, GM-CSF, IL-4, TNF-alpha, antibodies with the specificity of CD34, CD28, GM-CSF, IL-4, or TNF-alpha, etc.). Applicants are required to identify those claims that read on the elected invention. Each cell surface binding molecule is structurally and functionally distinct, recognized a different cell-surface receptor, and will necessitate independent searches. Accordingly, each combination of cell surface binding molecule and cell target constitutes an independent and distinct invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

**37 C.F.R. § 1.48(b)**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

***Interview Request***

Applicants request for an interview is noted. Applicants' representative is invited to contact the examiner to arrange for a convenient date and time.

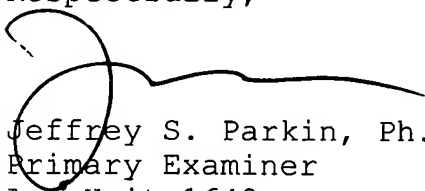
***Correspondence***

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. Informal communications (i.e., interview requests) may be sent to the examiner at [Jeffrey.Parkin@uspto.gov](mailto:Jeffrey.Parkin@uspto.gov). The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

03 February, 2008